IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

SOUTH MOUNTAIN CREAMERY, LLC,	:	
Plaintiff	:	**No. 1:18-cv-00738**
	:	
v.	:	**(Judge Kane)**
	:	
U.S. FOOD AND DRUG ADMINISTRATION, et al.,	:	
Defendants	:	

MEMORANDUM

Before the Court is the U.S. Food and Drug Administration ("FDA") and Commissioner Scott Gottlieb, M.D. ("Commissioner Gottlieb") (collectively, the "Federal Defendants")' motion (Doc. No. 37) to dismiss Plaintiff South Mountain Creamery, LLC ("Plaintiff")'s complaint (Doc. No. 1) for lack of subject-matter jurisdiction. For the reasons provided below, the Court will grant the Federal Defendants' motion and dismiss Plaintiff's claims against the Federal Defendants without prejudice.

I. BACKGROUND

A. Procedural Background

Plaintiff initiated the above-captioned action by filing a complaint on April 5, 2018. (Doc. No. 1.) The two-count complaint asserts First Amendment claims of unconstitutional censorship (Count I) and unconstitutional compulsion of misleading and confusing speech (Count II) relating to FDA regulation of the labeling of additive-free skim milk, which Plaintiff produces and seeks to sell in the Commonwealth of Pennsylvania. (Id. at 19-24.) Plaintiff asserts those claims against the Federal Defendants and Defendant Russell C. Redding, the Pennsylvania Secretary of Agriculture ("Defendant Redding"). (Id.) Plaintiff seeks declaratory

and injunctive relief "to protect the Creamery's right to tell the truth and honestly label additive-free skim milk as 'skim milk.'" (Id. ¶ 62.) On May 1, 2018, Defendant Redding filed an answer in response to Plaintiff's complaint. (Doc. No. 15.) On July 11, 2018, the Federal Defendants filed a motion to dismiss for lack of subject-matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). (Doc. No. 24.) The Court, constrained to construe the motion as a facial attack, denied the Federal Defendants' motion without prejudice. (Doc. No. 35.) The Federal Defendants subsequently filed the instant motion to dismiss for lack of subject-matter jurisdiction. (Doc. No. 37.) Because the motion is fully briefed (Doc. Nos. 38, 43, 46-48), it is ripe for disposition.

B. Factual Background[1]

1. South Mountain Creamery

The allegations in the complaint stem from Plaintiff's purported apprehension to sell additive-free skim milk that does not comply with federal labeling requirements. (Doc. No. 1.) Plaintiff is a creamery located in Frederick County, Maryland and is owned by Randy and Karen Sowers and their family members. (Id. ¶ 2.) Plaintiff produces and sells dairy products, including milk, yogurt, and cheese. (Id. ¶ 10.) Plaintiff purports to embrace a "responsible farming philosophy" and a "natural, additive-free approach." Its preference is to sell its milk with no added ingredients, although it does not object to pasteurization. (Id. ¶ 14.) Plaintiff explains that during the skimming process, in which whole milk becomes skim milk, the cream—which contains fat-soluble vitamins, including vitamins A and D—is skimmed and removed from the milk. (Id. ¶¶ 47-49.) Thus, according to Plaintiff, additive-free skim milk

[1] Unless otherwise noted, the following background information is derived from Plaintiff's complaint. (Doc. No. 1.)

contains lower levels of Vitamins A and D than whole milk. (Id. ¶¶ 49, 50.) Plaintiff contends that even if the removed Vitamins A and D are added back to the skim milk, however, the vitamins will substantially dissipate because they are fat-soluble and the fat has been removed. (Id. ¶¶ 15-17.)

Plaintiff wishes to label its additive-free skim milk in an "honest, non[-]misleading" manner and not to be constrained to labeling its product as "imitation."[2] (Id. ¶¶ 18, 61-63.) Plaintiff contends that over a decade ago, owner Randy Sowers met with FDA officials, who told him that the FDA requires additive-free skim milk to be labeled with the term "imitation." (Id. ¶ 85.) Plaintiff alleges that after it decided to pursue the idea of selling its additive-free skim milk in Pennsylvania, it contacted Pennsylvania officials in November of 2017 to discuss whether it could sell its additive-free skim milk in Pennsylvania with the label "skim milk." (Id. ¶¶ 23, 24.) Plaintiff contends that Pennsylvania officials stated that although the Commonwealth did not have any independent objections to labeling additive-free skim milk as "skim milk," the Commonwealth was required to enforce federal statutes and regulations requiring additive-free skim milk to be labeled as "imitation" if sold across state lines. (Id. ¶¶ 25, 26.) Plaintiff avers that it received a letter from the Pennsylvania Governor's Office of General Counsel stating that if the FDA did not have a problem with Plaintiff's labeling, the Commonwealth would not object to it, either. (Id. ¶ 27.) Plaintiff contends that federal law and FDA regulations unambiguously prohibit additive-free skim milk from being labeled as "skim milk" without the label of "imitation." (Id. ¶ 28.) Plaintiff further contends that pursuant to these statutes and regulations, additive-free skim milk is considered misbranded unless it is labeled as "imitation milk,"

[2] Plaintiff notes that it "would happily use any reasonable label that allows it to honestly and clearly describe its pure skim milk without being forced to mislead or confuse its customers." (Id. ¶ 63.)

"imitation skim milk," or "imitation milk product." (Id. ¶ 58.) Plaintiff alleges that its inability to sell its additive-free skim milk with an "honest, non[-]misleading" label has caused it substantial financial harm. (Id. ¶ 111.)

The Federal Defendants represent that Dr. Susan Mayne, director of the FDA's Center for Food Safety and Applied Nutrition ("CFSAN"), sent Plaintiff a letter on July 10, 2018, after this litigation began, in which she states that CFSAN plans to take no action to require additive-free skim milk to be labeled as "imitation." (Doc. No. 37-3 at 2.) Dr. Mayne's letter also provides several labeling options for Plaintiff,[3] along with an offer to discuss other possible labeling options. (Id.) The letter notes that the FDA has been unable to identify a single instance in which it has taken any misbranding enforcement action related to additive-free skim milk. (Id. at 2-3.) In declarations to the Court, Dr. Mayne notes that she is unaware of any contact between Plaintiff and the FDA regarding labeling requirements for additive-free skim milk between 2002 and the initiation of the instant action. (Doc. No. 37-2 at 5-7.) Dr. Mayne also asserts that, had Plaintiff contacted the FDA before filing this lawsuit as suggested to Plaintiff by Pennsylvania officials, the FDA would have taken the same position articulated in the FDA's July 10 letter. (Id. at 9.) Dr. Mayne further states that CFSAN's position was discussed and reviewed at length by top FDA officials, including "leadership in the Office of Compliance, the Office of Nutrition and Food Labeling, and the Office of Regulations and Policy," and CFSAN does not plan to change its position. (Id.) The Federal Defendants represent that Dwight-Jared Smith of the Pennsylvania Governor's Office of General Counsel sent a letter to Plaintiff, dated July 13, 2018,

[3] These options include: "(a) 'Non-fortified skim milk, 0% DV vitamins A&D'; (b) 'Non-fortified non-fat milk, 0% DV vitamins A&D'; (c) 'Skim milk, 0% DV vitamins A&D'; [and] (d) 'Non-fat milk, 0% DV vitamins A&D.'" (Doc. No. 24-1 at 2.)

that reaffirms the Commonwealth's position that any labeling deemed acceptable by the FDA will also be deemed acceptable by the Commonwealth. (Doc. No. 38 at 12.)

2. Statutes and Regulations at Issue

Plaintiff identifies several statutes and regulations that allegedly require it to label its additive-free skim milk as "imitation." (Doc. No. 1 at 8-11.) 21 U.S.C. § 343 provides that a food shall be considered misbranded "[i]f it is offered for sale under the name of another food," "[i]f it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated," or "[i]f it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard." See 21 U.S.C. §§ 343(b), (c), (g). 21 U.S.C. § 331 prohibits the receipt and delivery of misbranded food in interstate commerce and sets forth a corresponding penalty of up to one year of imprisonment and a fine of up to $1,000. See id. §§ 331(c), 333(a)(1).

Pursuant to 21 C.F.R. § 101.3(e), "a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated." See id. § 101.3(e). 21 C.F.R. § 131.110 defines "milk"[4] and provides that vitamins may be added to milk optionally.

[4] 21 C.F.R. § 131.110(a) states as follows:

> Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8 1/4 percent milk solids not fat and not less than 3 1/4 percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk,

See id. § 131.110(a), (b). 21 C.F.R. § 101.62(b) explains the criteria for the use of the term "skim" before "milk." See id. § 101.62(b). This provision addresses a reduction in fat content but does not address a reduction in vitamins. See id. In order for a food to be labeled with a nutrient content claim and a standardized term, "[n]utrients [must] be added to the food to restore nutrient levels so that the product is not nutritionally inferior . . . to the standardized food." See id. § 130.10(b). Nutritional inferiority includes "any reduction in the content of an essential nutrient that is present in a measurable amount." See id. § 101.3(e)(4). Vitamins A and D are amongst the FDA's list of essential nutrients. See id. § 101.9(c)(8)(iv). A food product is deemed an imitation "if it is a substitute for and resembles another food but is nutritionally inferior to that food." See id. § 101.3(e)(1). "Milk product," as defined by federal regulation, includes skim milk. See id. § 1240.3(j).

II. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(b)(1), a court may dismiss a claim for lack of subject-matter jurisdiction. See Fed. R. Civ. P. 12(b)(1). The Court must first determine whether the moving party's attack on the claim is facial or factual, "because that distinction determines how the pleading must be reviewed." See Constitution Party v. Aichele, 757 F.3d 347, 357 (3d Cir. 2014) (citing In re Schering Plough Corp. Intron, 678 F.3d 235, 243 (3d Cir. 2012)). In reviewing a facial attack, a court must apply the same standard of review as it does in the context of a Rule 12(b)(6) motion, considering only the allegations of the complaint, the documents referenced in the complaint, and any exhibits attached to the complaint in the light

> dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

21 C.F.R. § 131.110(a).

most favorable to the plaintiff. See id. at 358. In reviewing a factual attack, on the other hand, the Court may weigh and consider evidence beyond the pleadings. See id.

III. DISCUSSION

A. Legal Standard for the Justiciability of a Pre-enforcement Challenge

Article III of the Constitution limits the federal judiciary's jurisdiction to actual "cases or controversies." See U.S. CONST. art. III, § 2. "The existence of a case and controversy is a prerequisite to all federal actions, including those for declaratory or injunctive relief." Presbytery of the Orthodox Church v. Florio, 40 F.3d 1454, 1462 (3d Cir. 1994) (citing Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993); Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671 (1950)). Courts enforce this requirement "'through the several justiciability doctrines that cluster about Article III,' including 'standing, ripeness, mootness, the political-question doctrine, and the prohibition on advisory opinions.'" See Plains All Am. Pipeline L.P. v. Cook, 866 F.3d 534, 539 (3d Cir. 2017) (quoting Toll Bros., Inc. v. Twp. of Readington, 555 F.3d 131, 137 (3d Cir. 2009)). Non-justiciable claims are not properly suited for resolution by federal courts. See, e.g., Rucho v. Common Cause, 139 S. Ct. 2484, 2491 (2019). Accordingly, a court may dismiss such claims for lack of subject-matter jurisdiction. See Fed. R. Civ. P. 12(b)(1); Long v. Se. Pa. Transp. Auth., 903 F.3d 312, 320 (3d Cir. 2018).

The Third Circuit has noted that in the context of pre-enforcement challenges, the justiciability issue "can equally be described in terms of standing" as in terms of ripeness. See Plains, 866 F.3d at 539 (citing MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 128 n.8 (2007); Free Speech Coal., Inc. v. Att'y Gen. of United States, 825 F.3d 149, 167 n.15 (3d Cir. 2016); Presbytery, 40 F.3d at 1462)); see also Susan B. Anthony List v. Driehaus, 573 U.S. 149, 157 n.5 (2014) (hereinafter SBA List) (citing DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 335

(2006); MedImmune, 549 U.S. at 128 n.8) (explaining that the Court chose to use the term "standing" in its opinion, but noting that "[t]he doctrines of standing and ripeness 'originate' from the same Article III limitation" and "the Article III standing and ripeness issues in this case 'boil down to the same question'"). The Third Circuit applies a three-step test, first articulated in Step-Saver Data Systems, Inc. v. Wyse Technology, 912 F.2d 643 (3d Cir. 1990), to assess justiciability in the context of declaratory judgment cases. See Plains, 866 F.3d at 539-40 (citing Khodara Envtl., Inc. v. Blakey, 376 F.3d 187, 196 (3d Cir. 2004); Step-Saver, 912 F.2d). Under the Step-Saver test, a court must consider "(1) the adversity of the parties' interests, (2) the conclusiveness of the judgment, and (3) the utility of the judgment." See id. at 540 (quoting Khodara, 376 F.3d at 196) (internal quotation marks omitted). The Third Circuit has noted that the Step-Saver test "is merely a different framework for conducting the same justiciability inquiry" as the ripeness test set forth in Abbott Laboratories v. Gardner, 387 U.S. 136 (1967) (hereinafter Abbott Labs), abrogated on other grounds by Califano v. Sanders, 430 U.S. 99 (1977),[5] and the standing test set forth in SBA List.[6] See id. In a court's application of the Step-Saver test, "Abbott Labs's 'hardship' and 'fitness' factors still guide [the court's] analysis, as does the standing test set forth in SBA List." See id.

[5] In Abbott Labs, the Supreme Court held that in determining whether a case is ripe, a court must consider (1) "the fitness of the issues for judicial decision" and (2) "the hardship to the parties of withholding court consideration." See Abbott Labs, 387 U.S. at 149.

[6] In SBA List, the Supreme Court held that to have standing, a plaintiff must show the following: "(1) an 'injury in fact,' (2) a sufficient 'causal connection between the injury and the conduct complained of,' and (3) a 'likel[ihood]' that the injury 'will be redressed by a favorable decision.'" See SBA List, 573 U.S. at 157-58 (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). The Supreme Court further held that in determining whether an injury-in-fact has been sufficiently alleged in a pre-enforcement context, a court must consider whether the plaintiff has alleged a credible threat of enforcement. See id. at 159-61.

B. Parties' Arguments

The Federal Defendants argue that because they are not blocking or hindering Plaintiff's preferred labeling method, there is no proper case or controversy under Article III. (Doc. No. 38 at 14.) They argue that (1) Plaintiff lacks Article III standing and (2) Plaintiff's claims are not ripe. (Id. at 15-26.) In response, Plaintiff argues that (1) the Federal Defendants have again failed to assert a proper factual challenge, (2) Plaintiff's claims are ripe under Third Circuit precedent, and (3) contrary to the Federal Defendants' characterization of the case, this case's justiciability is more properly examined through the lens of mootness. (Doc. No. 43 at 13-27.) Plaintiff asserts that its claims are justiciable and, therefore, the Federal Defendants' motion must be denied. (Id. at 27.)

In regard to standing, the Federal Defendants argue that Plaintiff has failed to allege an injury in fact because it has failed to allege a credible threat of prosecution. (Doc. No. 38 at 15-19.) They argue that the FDA's assurances that it will not take any enforcement action against Plaintiff requiring its additive-free skim milk to be labeled as "imitation" negates Plaintiff's claim that it is at risk of enforcement action. (Id. at 16.) The Federal Defendants also argue that the absence of evidence that the FDA has ever taken enforcement action in a similar context further indicates the lack of a credible threat of enforcement. (Id. at 17-19.)

The Federal Defendants also assert that Plaintiff's claims are not ripe pursuant to the Step-Saver test. First, they argue that the interests of Plaintiff and the FDA are not adverse. (Id. at 21-23.) They contend that because the FDA has indicated that it has no intention of taking enforcement action against Plaintiff regarding its preferred labeling, Plaintiff does not face a substantial threat of real harm. (Id.) Next, the Federal Defendants argue that the claims cannot be conclusively decided without further factual development. (Id. at 23-25.) Specifically, they

argue that the Court would need to consider the specific labeling language in its analysis, and in the instant case, although the FDA has offered numerous labeling options to Plaintiff and offered to discuss other options with Plaintiff, Plaintiff has failed to engage with the FDA regarding the suggested labeling options or other potential options. (Id.) Finally, the Federal Defendants argue that the Court's issuance of a judgment at this time would serve no useful purpose in light of the positions taken by the FDA and the Commonwealth. (Id. at 25-26.) They claim that Plaintiff is not presently barred from taking the very action that it the subject of this case and, therefore, would suffer no hardship if the Court did not address its claims. (Id. at 26.)

In response, Plaintiff emphasizes that the proper framework for this case's justiciability analysis is mootness. (Doc. 43 at 26-27.) It relies on the FDA's July 10 letter, sent after the commencement of this lawsuit, in which the FDA states that it does not intend to take any enforcement action against Plaintiff but does not formally repudiate the challenged federal regulations. (Id. at 26-27.) Plaintiff urges that these assurances are unenforceable and fail to provide Plaintiff with a safe harbor from prosecution. (Id. at 17.) Thus, Plaintiff contends that the letter constitutes a voluntary cessation by the Federal Defendants. (Id. at 26-27.)

C. Whether Plaintiffs' Claims Are Justiciable[7]

[7] As an initial matter, the Court notes that it construes the Federal Defendants' motion as a factual attack, rather than a facial attack, on Plaintiff's complaint. For a 12(b)(1) motion to be construed as a factual attack, it must "concern 'the actual failure of [a plaintiff's] claims to comport [factually] with the jurisdictional prerequisites.'" See Lincoln Ben. Life Co. v. AEI Life, LLC, 800 F.3d 99, 105 (3d Cir. 2015) (alterations in original) (quoting CNA v. United States, 535 F.3d 132, 139 (3d Cir. 2008)). Here, by providing Dr. Mayne's signed declarations and July 10 letter as exhibits to their motion to dismiss, the Court concludes that the Federal Defendants triggered a factual challenge by presenting facts in competition with those asserted in Plaintiff's complaint.

The Court applies the Step-Saver test to determine whether Plaintiff's pre-enforcement challenges are justiciable.[8] See Plains, 866 F.3d at 539-40.

1. Adversity of the Parties' Interests

Regarding the first prong of the Step-Saver test—the adversity of the parties' interests—the Court finds that adversity is lacking. In the context of a pre-enforcement challenge, for parties' interests to be adverse, there must be "a 'substantial threat of real harm'" and the threat must "remain real and immediate throughout the course of the litigation." See Plains, 866 F.3d 534, 541 (3d Cir. 2017) (internal quotation marks omitted) (quoting Presbytery, 40 F.3d at 1463). Plaintiff wishes to label its additive-free skim milk in an "honest, nonmisleading" manner and not to be constrained to label its product as "imitation." However, the FDA has indicated that it has no intention of taking enforcement action against Plaintiff for not labeling its milk as "imitation." In fact, the record indicates that the FDA has offered Plaintiff multiple alternative labeling options and even invited Plaintiff to discuss other possibilities. (Doc. No. 37-3 at 2.) Although the FDA allegedly indicated that Plaintiff would have to label its additive-free skim

[8] Although Plaintiff argues that its action is not a pre-enforcement challenge and mootness is the proper justiciability framework for its claims, the Court is not so persuaded. While the FDA indeed sent its July 10 letter after the initiation of this action, the FDA states that it has searched its records and cannot identify a single instance where the FDA has sought enforcement action against any entity to require it to label additive-free skim milk as "imitation." (Doc. 39-1 at 2-3.) Thus, the Court concludes that the doctrine of voluntary cessation does not apply, and that Plaintiff's claims are pre-enforcement challenges properly examined under a standing- and ripeness-based analysis pursuant to Step-Saver. Here, Plaintiff is challenging the constitutionality of a policy that it claims is chilling its protected speech, and the government has not taken any enforcement action against Plaintiff. These circumstances mirror those of other cases in which courts, including the Supreme Court, have characterized actions as pre-enforcement challenges and deemed standing- or ripeness-based analyses proper. See, e.g., SBA List, 573 U.S. at 161 (identifying the plaintiff's action as a pre-enforcement challenge and applying standing analysis to a First Amendment challenge of an Ohio statute where no enforcement action was pending, but the plaintiff alleged that its speech was nonetheless chilled).

milk as "imitation" over a decade ago, the lack of any subsequent enforcement action cuts against finding that the parties' interests are adverse. See SBA List, 573 U.S. at 164 (quoting Steffel v. Thompson, 415 U.S. 452, 459 (1974)) ("Past enforcement against the same conduct is good evidence that the threat of enforcement is not 'chimerical.'"); Behar v. Pa. Dep't of Transp., 791 F. Supp. 2d 383, 390 (M.D. Pa. 2011) (concluding in its pre-enforcement standing analysis that the plaintiff did not face a credible threat of prosecution in part because "the regulation ha[d] never been enforced" against similarly situated individuals). Several other facts support a finding that the parties' interests are not adverse—specifically, the lack of any indication from the FDA in the fifteen (15) years leading up to this lawsuit that it would take enforcement action against Plaintiff, the explicit assurance provided in the FDA's July 10 letter that it had no plan to do so, and the declaration by Dr. Mayne that the position provided by the FDA in the July 10 letter would have been the same had Plaintiff contacted the FDA before filing the instant action. See Presbytery, 40 F.3d at 1470-71 (holding that the representations by the Government that it has no intention to prosecute certain plaintiffs "clearly show that the claims [against those plaintiffs] . . . are not ripe"). Thus, the Court concludes that the adversity prong cuts against the justiciability of Plaintiff's claims.

2. The Conclusiveness of a Judgment

"Conclusiveness is a short-hand term for whether a declaratory judgment definitively would decide the parties' rights." Ne. Hub Partners, L.P. v. CNG Transmission Corp., 239 F.3d 333, 344 (3d Cir. 2001) (citing Step-Saver, 912 F.3d at 648). Under the second Step-Saver prong, courts consider whether the dispute is based on "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be in a hypothetical set of facts." See Plains, 866 F.3d at

542-43. "[T]wo concerns are paramount." See id. at 543. First, courts consider "whether 'the legal status of the parties' will 'be changed or clarified.'" See id. (quoting Travelers Ins. Co. v. Obusek, 72 F.3d 1148, 1155 (3d Cir. 1995)). Second, courts "ask 'whether further factual development . . . would facilitate decision' or [whether] 'the question presented is purely legal.'" See id. (quoting Ne. Hub Partners, 239 F.3d at 344).

A declaratory judgment would be inconclusive in the instant case. The FDA has offered multiple labeling options to Plaintiff, as well as an invitation to discuss other options. (Doc. No. 37-3 at 2.) Plaintiff has not specified the exact language with which it wishes to label its additive-free skim milk—it merely says that it objects to labeling its additive-free skim milk as "imitation" and that it "would happily use any reasonable label that allows it to honestly and clearly describe its pure skim milk without being forced to mislead or confuse its customers." (Doc. No. 1 at 61-65, 79-82.) The specific labeling restrictions at issue, however, are critically important for any First Amendment analysis conducted by the Court. For example, during a merits review, the Court must consider whether the purported restriction on Plaintiff's speech is more extensive than necessary to achieve the Government's goals. See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 569-70 (1980). Thus, if Plaintiff wishes to challenge restrictions imposed by the FDA beyond the "imitation" requirement, the underlying facts have not developed to the point that the Court has any specific labeling restrictions to address. Further, if Plaintiff merely wishes to challenge the imposition of the "imitation" requirement, a declaratory judgment would not "change[] or clarif[y]" the parties' legal statuses because the FDA has made clear that, no matter the outcome of this litigation, it does not intend to impose such a requirement. See Plains, 866 F.3d at 543 (quoting Travelers Ins. Co., 72 F.3d

at 1155). Because a declaratory judgment would be inconclusive, the second Step-Saver factor also weighs against a finding of justiciability.

3. The Utility of a Judgment

Finally, the third Step-Saver prong requires the Court to examine the utility of a declaratory judgment. See id. The Court considers "whether the parties' plans of actions are likely to be affected by a declaratory judgment," "the hardship to the parties of withholding judgment," and "whether the entry of judgment 'would be useful to the parties and others who could be affected.'" See id. at 543-44 (quoting Ne. Hub Partners, 239 F.3d at 344-45; Presbytery, 40 F.3d at 1470) (internal quotation marks omitted). The FDA has assured Plaintiff that it does not plan to take action to require Plaintiff to label its additive-free skim milk as "imitation," and, as discussed supra, the parties have failed to identify a dispute as to any other labeling options. Therefore, the Court concludes that a judgment would provide little practical utility in this case. See First Specialty Ins. Corp. v. Hudson Palmer Homes, Inc., No. 17-cv-5732, 2018 WL 6002318, at *5 (E.D. Pa. Nov. 14, 2018) ("However, because the Court does not have an adequate record for ruling on plaintiff's indemnity obligations, the Court cannot provide a declaratory judgment of 'significant utility.'"). Thus, Step-Saver's utility prong weighs against justiciability. Accordingly, because all three of the Step-Saver factors weigh against a finding of justiciability, the Court concludes that Plaintiff's claims against the Federal Defendants are not justiciable.

IV. CONCLUSION

Because Plaintiff lacks Article III standing to pursue its claims against the Federal Defendants,[9] the Court will grant the Federal Defendants' motion to dismiss for lack of subject-matter jurisdiction and dismiss Plaintiff's claims without prejudice. The Court will also direct Plaintiff to show cause why the Court should not dismiss Plaintiff's claims against Defendant Redding as non-justiciable.[10] An appropriate Order shall issue.

[9] Because the Court finds that Plaintiff's claims are not justiciable under the standing- and ripeness-based Step-Saver test, it declines to address mootness at length. Nevertheless, the Court finds that even if Plaintiff's claims against the Federal Defendants were justiciable under Step-Saver, the Court would find the case non-justiciable on mootness grounds. Here, the letter sent by the FDA to Plaintiff indicates that the FDA does not plan to take enforcement action requiring Plaintiff to label its additive-free skim milk as "imitation." (Doc. No. 37-3 at 2.) Even assuming arguendo that a live controversy existed at the time the instant action was filed, the July 10 letter rendered the issue moot.

[10] Although Defendant Redding has not filed a motion to dismiss for lack of subject-matter jurisdiction, "[c]ourts have an independent obligation to determine whether subject-matter jurisdiction exists, even when no party challenges it." See, e.g., Hertz Corp. v. Friend, 559 U.S. 77, 94 (2010). Thus, the Court may raise the issue of subject-matter jurisdiction sua sponte. See, e.g., Grp. Against Smog & Pollution, Inc. v. Shenango, Inc., 810 F.3d 116, 122 n.6 (3d Cir. 2016) (citing Henderson v. Shinseki, 562 U.S. 428, 434-35 (2011)). Nevertheless, the Third Circuit has instructed that it is improper for district courts to rule on subject-matter jurisdiction without first affording the parties the opportunity to brief or present evidence on the issue. See Neiderheiser v. Borough of Berwick, 840 F.2d 213, 216 n.6 (3d Cir. 1988); see also Liberty Mut. Ins. Co. v. Ward Trucking Corp., 48 F.3d 742, 755-56 & n.6 (3d Cir. 1995) (Becker, J., dissenting).